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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/687,470 | 10/16/2003 | Warren Stern | SOHN-P01-001 | 8880 |

28120 7590 05/11/2006

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| EXAMINER | |
|---|---|
| STITZEL, DAVID PAUL | |
| **ART UNIT** | **PAPER NUMBER** |
| 1616 | |

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/687,470 | STERN, WARREN | |
| | Examiner | Art Unit | |
| | David P. Stitzel, Esq. | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *2-4,7,10 and 12-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,8,9 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## OFFICIAL ACTION

### *Acknowledgment of Receipt*

Receipt of the Applicant's Election, with traverse, of: Invention I, encompassing claims 1 and 5-11; a proton pump inhibitor (i.e., an inhibitor of H+,K+-ATPase) as the patentably distinct species of inhibitor; and a compound of formula IX, namely lansoprazole (a.k.a., Prevacid, Zoton and Inhibitol), as the patentably distinct subspecies of a proton pump inhibitor, which was filed on February 16, 2006, in response to the Official Action mailed on December 27, 2005, is acknowledged.

### *Restriction/Election*

Applicant's traversal of the aforementioned restriction requirement on the grounds that said restriction requirement is improper and that a prior art search and examination of the claims of the inventions as set forth in Inventions I through IV, especially Inventions I and II, would not impose a serious search burden, is duly noted. However, a proper prima facie case of undue search burden associated with a prior art search and examination of the claims of the separate, distinct and independent inventions of Groups I through IV has previously been established in the aforementioned Official Action. For example, a method of treating sleep related respiratory disorders as set forth in Invention I has a different function and/or effect from the method of treating awake related respiratory disorders as set forth in Invention II. See, MPEP §§ 802.01 and 806.06. That is, Invention I has the function or effect of treating a respiratory disorder when a patient is asleep (i.e., sleep apnea), as opposed to the function or effect of treating a respiratory disorder when a patient is awake (i.e., asthma that is triggered by exposure to allergens and irritants, such as pollen, workplace chemicals and cigarette smoke). The aforementioned distinctness is further evidenced by the Applicant's filing of two separate independent claims, the first of which is solely directed to treating respiratory disorders

when a patient is asleep, whereas the second of which is solely directed to treating respiratory disorders when a patient is awake. As a result, the restriction requirement is deemed proper and therefore made FINAL.

Applicant's traversal of the aforementioned species and subspecies election on the grounds that said species and subspecies requirement is improper because said species and subspecies are encompassed by Markush groups that can be simultaneously examined without imposing a serious search burden, is duly noted. However, a proper prima facie case of undue search burden associated with a prior art search and examination of the following patently distinct species and subspecies: 1. a histamine $H_2$-receptor antagonist (i.e., subspecies comprising: Tagamet, Zantac, Pepcid and Axid); 2. a proton pump inhibitor (i.e., subspecies comprising: formulas I-XVIII, Prevacid, Nexium, Prilosec, Protonix and Aciphex); 3. a bismuth compound; 4. a synthetic somatostatin analog; 5. an antiemetic agent; 6. a sucralfate; 7. a prostaglandin analog; 8. a muscarinic cholinergic antagonist; 9. a D2 antagonist; 10. a chenodeoxycholic acid; 11. an ursodeoxycholic acid; and 12. a pancreatic enzyme preparation, has previously been established in the aforementioned Official Action. Because each of the disclosed species and subspecies are patentably distinct, each from the other, restriction for examination purposes as indicated is proper and therefore made FINAL.

***Status of Claims***

Claims 2-4, 7, 10 and 12-17 are withdrawn from further consideration as being directed to non-elected inventions, species and subspecies. As a result, claims 1, 5, 6, 8, 9 and 11, which are drawn to the elected Invention, species and subspecies, are currently pending and therefore examined herein on the merits for patentability.

***Claim Rejections - 35 U.S.C. § 102***

The following are quotations of the appropriate paragraphs of 35 U.S.C. § 102, which form the basis of the anticipation rejections as set forth under this particular section of the Official Action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 5, 6, 8, 9 and 11 are rejected under 35 U.S.C. § 102(e) as being anticipated by International Patent Application Publication WO03/097011A1 (hereinafter the Barth '011 publication).

With respect to claims 1, 5, 6, 8, 9 and 11 of the instant application, the Barth '011 publication discloses a method of treating gastroesophageal reflux disease (GERD), Zollinger-Ellison syndrome, gastric acid hypersecretion, sleep disorders, sleep apnea and snoring, wherein said method comprises: administering a therapeutically effective amount of at least one proton pump inhibitor (i.e., an inhibitor of H+,K+-ATPase), such as lansoprazole (a.k.a., Prevacid) (abstract; page 1, lines 8, 9, 22, 23 and 27; page 3, lines 10-13; page 8, lines 2-15; page 13, lines 20-21; page 19, lines 8-16 and 24-34; page 20, lines 1-7; page 27, lines 32-35; page 28, lines 4-7; claims 11-14 and 18).

2. Claims 1, 5, 6, 8, 9 and 11 are rejected under 35 U.S.C. §§ 102(a) and (e) as being anticipated by U.S. Patent 6,353,005 (hereinafter the Rubin '005 patent).

With respect to claims 1, 5, 6, 8, 9 and 11 of the instant application, the Rubin '005 patent discloses a method of treating gastroesophageal reflux disease (GERD), Zollinger-Ellison syndrome, and gastric hyperacidity, wherein said method comprises administering a composition comprising a therapeutically effective amount of at least one proton pump inhibitor (i.e., an inhibitor of H+,K+-ATPase), such as lansoprazole (a.k.a., Prevacid) (abstract; column 1, lines 1-30; column 3, lines 19-23, 36-39 and 45-50; column 6, lines 5-16; column 7, lines 1-27 and 50-59; column 8, lines 29-53; column 9, lines 15-29 and 58-67; column 10, lines 1-4; column 11, lines 7-15; column 12, lines 3-25; column 14, lines 37-38; claims 10 and 22). Although the Rubin '005 patent does not explicitly teach that that said method and corresponding composition is useful for treating sleep disorders, sleep apnea and snoring, the method of administering a composition comprising a therapeutically effective amount of at least one proton pump inhibitor (i.e., an inhibitor of H+,K+-ATPase), such as lansoprazole (a.k.a., Prevacid), would have inherently treated sleep disorders, sleep apnea and snoring, since said chemical composition comprising lansoprazole and its properties are inseperable.

The "discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." See *Atlas Powder Co. v. Ireco Inc.*, 51 USPQ 2d 1943, 1947 (Fed. Cir. 1999). Therefore, merely claiming a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); and MPEP § 2112. Furthermore "products of identical chemical composition can not have mutually exclusive properties," since a chemical composition and its properties are inseparable. See *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990); and MPEP § 2112. Therefore, if the prior

art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. See MPEP § 2112.

***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 5, 6, 8, 9 and 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over International Patent Application Publication WO03/053221A2 (hereinafter the ***Ieni '221 publication***) *in view of either* Senior BA, Khan M, Schwimmer C, Rosenthal L, Benninger M, "Gastroesophageal Reflux and Obstructive Sleep Apnea," Laryngoscope, Vol. 111, pp. 2144-2146 (December 2001) (hereinafter the ***Senior publication***), *or* Xiao GH, Wang ZF, Ke MY, and Huang XZ, "The Relationship Between Gastroesophageal Reflux Disease (GERD) and Obstructive Sleep Apnea

Syndrome (OSAS) and Effects of Anti-Reflux Therapy," Gastroenterology, Vol. 114, No. 4, Part 2, page 336 [G1373] (1998) (hereinafter the ***Xiao publication***).

With respect to claims 1, 5, 6, 8, 9 and 11 of the instant application, the ***Ieni '221 publication*** teaches a method of treating GERD, Zollinger-Ellison syndrome, gastric acid hypersecretion, and apnea, wherein said method comprises: administering a therapeutically effective amount of at least one proton pump inhibitor (i.e., an inhibitor of H+,K+-ATPase), including lansoprazole (a.k.a., Prevacid) and/or omeprazole (a.k.a., Prilosec) (abstract; page 1, lines 7-10 and 28-30; page 2, lines 1-3, 9-13 and 29-32; page 3, lines 1-3 and 20-25; page 4, lines 11-17 and 32; page 5, lines 1-3 and 31-32; page 6, lines 1-3; page 7, lines 15-19; page 8, lines 11-17; page 9, line 32; page 10, lines 1-4; page 15, lines 25-29; page 16, lines 5-20; page 17, lines 29-32; page 18, lines 1-3; claims 1, 2, 7, 8, 13 and 14). The Ieni '221 publication does not explicitly teach that the apneic disorder being treated is sleep apnea in particular, as instantly claimed.

However, ***Senior publication*** teaches a method of treating GERD and obstructive sleep apnea syndrome (OSAS), wherein said method comprises: administering a therapeutically effective amount of a proton pump inhibitor, namely omeprazole (page 2144, column 1, abstract; page 2144, column 2, lines 7-9; page 2145, column 1, lines 26-27, 36-38, 43-44 and 47-56; page 2145, column 2, lines 1-9 and 55-57; page 2146, column 1, lines 1-2 and 5-7).

However, ***Xiao publication*** teaches a method of treating GERD and OSAS, wherein said method comprises: administering a therapeutically effective amount of a proton pump inhibitor, namely omeprazole (page 336, [G1373]).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed that the method of treating apnea, as broadly recited, via the administration of a

therapeutically effective amount of one or more proton pump inhibitor, including lansoprazole and/or omeprazole, as taught by the Ieni '221 publication, would have also been useful in treating specific types of apnea not explicitly recited within the Ieni '221 publication, such as sleep apnea, and in particular OSAS, as reasonably suggested by the Senior publication and the Xiao publication. One of ordinary skill in the art at the time the instant application was filed would have been motivated to treat GERD and OSAS by substituting lansoprazole for omeprazole within the methods taught by the Senior publication and the Xiao publication, since the Ieni '221 publication reasonably suggests the interchangeability of lansoprazole and omeprazole for treating GERD and apneic disorders. One of ordinary skill in the art at the time the instant application was filed would have had a reasonable expectation of success in utilizing lansoprazole in place of omeprazole for the treatment of GERD and OSAS, since both the Senior publication and the Xiao publication teach administering a proton pump inhibitor, namely omeprazole, for the treatment of GERD and OSAS, and the Ieni '221 publication reasonably suggests the interchangeability of lansoprazole and omeprazole for treating GERD and apneic disorders.

***Conclusion***

Claims 1, 5, 6, 8, 9 and 11 are rejected because the claimed invention would have been anticipated and/or prima facie obvious to one of ordinary skill in the art at the time the invention was made since each and every element of the claimed invention, as a whole, is disclosed in and/or would have been reasonably suggested by the teachings of the cited prior art references.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq. whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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